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**WARNING LETTER**

**NWE-03-02W**

VIA FEDERAL EXPRESS

November 28, 2001

Michael Parascandolo  
President  
N. Parascandolo & Sons, Inc.  
Perry Mill Wharf  
Newport, RI 02840

Dear Mr. Parascandolo:

We inspected your firm, located at Perry Mill Wharf, Newport, RI, on October 23 and 25, 2001 and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation causes your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviation was as follows:

1. You must implement the recordkeeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving critical control point to control the histamine hazard listed in your HACCP plan for bluefish. We have received your revised HACCP plan for histamine producing fish, dated October 31, 2001. We note that your firm is continuing to control the histamine hazard through the harvest vessel control strategy. Therefore, you will need to document your review of harvest vessel records for every lot received.

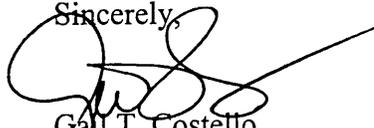
We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to the European Union (EU) countries if you do not correct this deviation.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your current monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail T. Costello  
District Director  
New England District Office